DOCKET NO.: MPCI-0033

Application No.: 09/928,467

Office Action Dated: January 15, 2004

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO

37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 82, 85, 87-105 are cancelled, claims 83, 84, and 86 are amended, and claims 106-134 are added as follows:

1-82. (Canceled)

83. (Amended) The formulation of claim [[82]] 106 wherein said stabilizer is ethanol, acetone, glycerin, propylene glycol, polyethylene glycol, isopropyl alcohol, methanol, or polysorbates.

84. (Amended) The formulation of claim [[82]] 106 wherein said stabilizer is ethanol.

85. (Cancelled)

86. (Amended) The formulation of claim [[82]] 106 wherein the anion of a mineral acid is chloride ions.

87-105 (Cancelled)

106. (New) A stable pharmaceutical formulation in dry dosage form comprising: gabapentin crystals

a mineral acid present in an amount to provide at least 20 ppm of the anion of the mineral acid, based on the weight of gabapentin, said mineral acid dispersed throughout each gabapentin crystal; and

at least one stabilizer,

wherein said formulation contains less than 1% by weight of the lactam degradation product of gabapentin after being stored for 3 months at 40 degrees Centigrade and 75 % relative humidity.

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107. (New) The dry dosage form of claim 106 wherein the mineral acid is present in an amount to provide from 20 ppm to about 55 ppm of the anion of the mineral acid, based on the weight of gabapentin.

108. (New) The dry dosage form of claim 106 wherein the mineral acid is present in an amount to provide from 20 ppm to about 40 ppm of the anion of the mineral acid, based on the weight of gabapentin.

109. (New) The dry dosage form of claim 106 prepared by the steps of:
dissolving the mineral acid in the stabilizer,
wetting gabapentin with the mineral acid solution, and
removing a substantial part of the stabilizer to form the gabapentin crystals.

110. (New) The dry dosage form of claim 109 prepared by the method further comprising the steps of:

dry-mixing the gabapentin crystals and a pharmaceutically acceptable adjuvant.

- 111. (New) The dry dosage form of claim 106 further comprising at least one pharmaceutically acceptable adjuvant.
- 112. (New) A method of preparing stable pharmaceutical formulations in dry dosage form comprising the steps of:

dissolving a mineral acid in a stabilizer,

wetting gabapentin with the mineral acid solution, and

removing a substantial portion of the stabilizer to form gabapentin crystals comprising gabapentin molecules and a mineral acid present in an amount to provide at least 20 ppm of an anion of the mineral acid, based on the weight of gabapentin, said mineral acid dispersed throughout each gabapentin crystal, wherein said formulation contains less than 1%

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by weight of the lactam degradation product of gabapentin after being stored for 3 months at

40 degrees Centigrade and 75 % relative humidity.

113. (New) A stable pharmaceutical formulation in dry dosage form comprising:

crystals of at least one cyclic amino acid which is susceptible to formation of a

lactam:

a mineral acid present in an amount to provide at least 20 ppm of the anion of the

mineral acid, based on the weight of the at least one cyclic amino acid, said mineral acid

dispersed throughout each crystal of the at least one cyclic amino acid; and

at least one stabilizer,

wherein said formulation contains less than 1% by weight of the lactam degradation product

of the at least one cyclic amino acid after being stored for 3 months at 40 degrees Centigrade

and 75 % relative humidity.

114. (New) The dry dosage form of claim 113 wherein the mineral acid is present in an

amount to provide from 20 ppm to about 55 ppm of the anion of the mineral acid, based on

the weight of the cyclic amino acid.

115. (New) The dry dosage form of claim 113 wherein the mineral acid is present in an

amount to provide from 20 ppm to about 40 ppm of the anion of the mineral acid, based on

the weight of the cyclic amino acid.

116. (New) The dry dosage form of claim 113 prepared by the steps of

dissolving the mineral acid in the stabilizer,

wetting the at least one cyclic amino acid which is susceptible to formation of

a lactam with the mineral acid solution, and

removing a substantial part of the stabilizer to form the crystals of the cyclic

amino acid.

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117. (New) The dry dosage form of claim 113 further comprising at least one pharmaceutically acceptable adjuvant.

118. (New) The formulation of claim 113 wherein said stabilizer is ethanol, acetone, glycerin, propylene glycol, polyethylene glycol, isopropyl alcohol, methanol, or polysorbates.

119. (New) The formulation of claim 113 wherein the stabilizer is ethanol.

120. (New) The formulation of claim 113 wherein the anion of a mineral acid is chloride ions.

121. (New) A method of preparing stable pharmaceutical formulations in dry dosage form comprising the steps of:

dissolving a mineral acid in a stabilizer,

wetting a cyclic amino acid which is susceptible to formation of a lactam with the mineral acid solution, and

removing a substantial part of the stabilizer to form crystals of the cyclic amino acid, said crystals comprising the cyclic amino acid and a mineral acid present in an amount to provide at least 20 ppm of an anion of the mineral acid, based on the weight of the cyclic amino acid, said mineral acid dispersed throughout each crystal of the cyclic amino acid, wherein said formulation contains less than 1% by weight of the lactam after being stored for 3 months at 40 degrees Centigrade and 75 % relative humidity.

122. (New) A gabapentin raw material comprising:

gabapentin crystals

a mineral acid present in an amount to provide at least 20 ppm of the anion of the mineral acid, based on the weight of gabapentin, said mineral acid dispersed throughout each gabapentin crystal; and

at least one stabilizer,

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wherein said formulation contains less than 1% by weight of the lactam degradation product

of gabapentin after being stored for 3 months at 40 degrees Centigrade and 75 % relative

humidity.

123. (New) The gabapentin raw material of claim 122 wherein the mineral acid is present in

an amount to provide from 20 ppm to about 55 ppm of the anion of the mineral acid, based on

the weight of gabapentin.

124. (New) The gabapentin raw material of claim 122 wherein the mineral acid is present in

an amount to provide from 20 ppm to about 40 ppm of the anion of the mineral acid, based on

the weight of gabapentin.

125. (New) A cyclic amino acid raw material comprising:

crystals of a cyclic amino acid which is susceptible to formation of a lactam

a mineral acid present in an amount to provide at least 20 ppm of the anion of

the mineral acid, based on the weight of the cyclic amino acid, said mineral acid dispersed

throughout each crystal; and

at least one stabilizer.

wherein said formulation contains less than 1% by weight of the lactam degradation product

of the cyclic amino acid after being stored for 3 months at 40 degrees Centigrade and 75 %

relative humidity.

126. (New) The cyclic amino acid raw material of claim 125 wherein the mineral acid is

present in an amount to provide from 20 ppm to about 55 ppm of the anion of the mineral

acid, based on the weight of the cyclic amino acid.

127. (New) The gabapentin raw material of claim 125 wherein the mineral acid is present in

an amount to provide from 20 ppm to about 40 ppm of the anion of the mineral acid, based on

the weight of the cyclic amino acid.

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128. (New) The dosage form of claim 106 wherein said stabilizer is a semi polar, organic

liquid with a dielectric constant below 60.

129. (New) The dosage form of claim 113 wherein said stabilizer is a semi polar, organic

liquid with a dielectric constant below 60.

130. (New) The method of claim 112 further comprising the step of:

dry-mixing the gabapentin crystals with a pharmaceutically acceptable adjuvant.

131. (New) The method of claim 121 further comprising the step of:

dry-mixing the cyclic amino acid crystals with a pharmaceutically acceptable

adjuvant.

132. (New) The dosage form of claim 117 prepared by the method further comprising the

steps of:

dry-mixing the crystals of cyclic amino acid with the pharmaceutically acceptable

adjuvant.

133. (New) The dosage form of claim 106 wherein the mineral acid in each gabapentin

crystal is uniformly dispersed.

134. (New) The dosage form of claim 113 wherein the mineral acid in each crystal of amino

acid is uniformly dispersed.